Care Models and Associated Outcomes in Congenital Heart Surgery

WHAT'S KNOWN ON THIS SUBJECT: Recently, there has been a shift toward care of patients undergoing congenital heart surgery in dedicated pediatric cardiac ICUs. The impact of this trend on patient outcomes is unclear.

WHAT THIS STUDY ADDS: In an analysis of 20 922 patients from 47 centers we were unable to detect a difference overall in postoperative morbidity or mortality associated with a dedicated cardiac ICU. There may be a survival benefit in certain subgroups.

abstract

OBJECTIVE: Recently, there has been a shift toward care of children undergoing heart surgery in dedicated pediatric cardiac intensive care units (CICU). The impact of this trend on patient outcomes is unclear. We evaluated postoperative outcomes associated with a CICU versus other ICU models.

PATIENTS AND METHODS: Society of Thoracic Surgeons Congenital Heart Surgery Database participants (2007–2009) who completed an ICU survey were included. In multivariable analysis, we evaluated outcomes associated with a CICU versus other ICUs, adjusting for center volume, patient factors, and Society of Thoracic Surgeons–European Association for Cardiothoracic Surgery surgical risk category.

RESULTS: A total of 20 922 patients (47 centers; 25 with a CICU) were included. Overall unadjusted mortality was 3.8%, median length of stay was 6 days (interquartile range: 4–13), and 21% had 1 or more complications. In multivariable analysis, there was no difference in mortality comparing CICUs versus other ICUs (odds ratio: 0.88 [95% confidence interval: 0.65–1.19]). In stratified analysis, CICUs were associated with lower mortality only among those in Society of Thoracic Surgeons–European Association for Cardiothoracic Surgery category 3 (odds ratio: 0.47 [95% confidence interval: 0.25–0.86]), primarily related to atrioventricular canal repair and arterial switch operation. There was no difference in length of stay or complications overall or in stratified analysis.

CONCLUSIONS: We were not able to detect a difference in postoperative morbidity or mortality associated with the presence of a dedicated CICU for children undergoing heart surgery. There may be a survival benefit in certain subgroups . *Pediatrics* 2011;127:e1482–e1489

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KEY WORDS

congenital heart surgery, outcomes

ABBREVIATIONS

CICU—cardiac ICU
STS—Society of Thoracic Surgeons
STS-EACTS—Society of Thoracic Surgeons–European Association for Cardiothoracic Surgery

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Outcomes in children undergoing heart surgery have improved dramatically over the past 3 decades due to refinement in surgical techniques and advancements in perioperative care.[1] However, evidence to guide optimal care is still evolving, and there are few best-practice guidelines. Recently, there has been a shift toward providing postoperative care in dedicated pediatric cardiac ICUs (CICUs) versus general PICUs or NICUs.[2,3] A survey of US centers found that 45% now provide care for patients undergoing congenital heart surgery in a dedicated CICU, and the presence of a CICU is used as a measure of quality in ranking US pediatric heart surgery programs.[4,5]

However, the impact of a dedicated CICU on patient outcomes following congenital surgery has not been evaluated to date. Several adult and pediatric studies[6–13] support the notion that the cohorting of patients with certain conditions, and specialized care or use of standardized treatment protocols, may improve outcomes. The purpose of this study was to evaluate postoperative outcomes associated with a dedicated CICU versus other ICU care models in a multi-institutional population undergoing congenital heart surgery.

PATIENTS AND METHODS

Data Source

This study used data from an ICU survey linked to data from the Society of Thoracic Surgeons (STS) Congenital Heart Surgery Database. As previously described, a survey regarding ICU care models was administered in 2009 to US centers caring for patients undergoing congenital heart surgery.[4] Data regarding ICU structure from this survey were subsequently reviewed by a panel of cardiologists, critical care physicians, and congenital heart surgeons and verified through direct contact with the program, personal knowledge, and Internet searches. For the purposes of this analysis, a CICU was defined as a freestanding unit dedicated to the care of pediatric patients with congenital and acquired heart disease. Other ICU care models, including general PICU, NICU, and CICUs within a general PICU, were classified as "other ICU."

Survey data were subsequently deidentified and linked to data from the STS Congenital Heart Surgery Database using a numerical coding system that the investigators were blinded to. The STS is a not-for-profit organization representing surgeons, researchers, and allied health professionals dedicated to ensuring the best care for patients undergoing cardiothoracic surgery. The STS National Database, the largest cardiothoracic surgery clinical data registry in the world, includes 3 components: (1) the Adult Cardiac Surgery Database; (2) the General Thoracic Surgery Database; and (3) the Congenital Heart Surgery Database. Although data are collected primarily for quality-improvement purposes, the STS National Databases also are used extensively in outcomes research with more than 100 publications to date.[14] The STS Congenital Heart Surgery Database currently contains deidentified data on more than 160 000 surgeries conducted because 1998 performed at 85 centers in 37 states, representing nearly three-quarters of all US centers performing congenital heart surgery.[15] Data collected include perioperative, operative, and outcomes data on all patients undergoing congenital heart surgery at participating centers. Data quality and reliability are assured through intrinsic verification of data and a formal process of site visits and data audits.[16] The Duke Clinical Research Institute serves as the data warehouse and analysis center for all of the STS National Databases. Research performed on the STS Database at the Duke Clinical Research Institute is reviewed by the Duke University Institutional Review Board. Because the data used for research represent a limited data set that was originally collected for nonresearch purposes, and the investigators do not know the identity of individual patients, the analysis of these data was declared by the Duke Institutional Review Board to be research not involving human subjects. This study was also reviewed and approved by the STS Access and Publications Committee.

Study Population

Of 85 US centers who have submitted data to the STS Congenital Heart Surgery Database at any time from 1998 to present, 57 US centers that completed the ICU survey in 2009 and submitted data to the STS Congenital Heart Surgery Database from 2007 to 2009 were eligible for inclusion. Centers who changed their care model during the study period ($n = 2$), and those with more than 15% missing data for key study variables, were excluded ($n = 8$). Although the STS Database contains nearly complete data for the core data fields regarding procedure and in-hospital mortality, not all centers submit complete data for the other variables in the STS Database. Therefore, it is standard practice to exclude centers with more than 15% missing data for key study variables, to maximize data integrity and minimize missing data.[17] This left 47 centers in the final study population. Included centers were similar to the overall cohort submitting data to the STS Database during this time period with regard to outcome (in-hospital mortality: 3.8% vs 3.9%; median postoperative length of stay: 6 days vs 6 days, respectively).

Patients from included centers undergoing any surgery classified in the STS-European Association for Cardiothoracic

Surgery (STS-EACTS) risk stratification system were included (category 1: lowest mortality risk [0.8%], category 5: highest mortality risk [23.1%]).[18] This system recently was developed on the basis of empiric data from nearly 80 000 patients, and a complete listing of the specific operations contained within each risk category has been previously published.[16] This system includes a greater number of operations compared with other risk-stratification systems.[19,20] Patients aged older than 18 years and those who weighed less than 2500 g undergoing patent ductus arteriosus ligation were excluded. Only the first cardiovascular operation of the admission was analyzed.

Data Collection

Data collection included demographics, the presence of any noncardiac abnormality or genetic syndrome (defined in the STS Database as asplenia, polysplenia, Down syndrome, Turner syndrome, DiGeorge, Williams-Beuren syndrome, Alagile syndrome, 22q11 deletion, rubella, Marfan syndrome, or any other chromosomal or syndromic abnormality), the presence of other preoperative factors (defined in the STS Database as preoperative mechanical circulatory or mechanical ventilatory support, tracheostomy, complete atrioventricular heart block, arrhythmia, shock, acidosis, pulmonary hypertension, renal failure, bleeding disorder, sepsis or endocarditis, and neurologic deficit or seizures), the duration of preoperative length of stay, and the number of previous cardiothoracic surgeries. The primary operation performed was classified by STS-EACTS risk category.[18] Finally, center characteristics also were collected, including center region and average annual center surgical volume of STS-EACTS–classified cases during the study period.

Outcome

The primary outcome was in-hospital mortality. Secondary outcomes included postoperative length of stay and postoperative complications as defined in the STS Database (including bleeding requiring reoperation, acute renal failure requiring temporary or permanent dialysis, transient or persistent neurologic deficit, new-onset seizures, wound or sternal dehiscence, wound infection, septicemia, mediastinitis, endocarditis, respiratory insufficiency requiring reintubation or mechanical ventilatory support greater than 7 days postoperatively, cardiac arrest, mechanical circulatory support, or arrhythmia).

Analysis

Patient and center characteristics were described using standard summary statistics and compared between the 2 ICU groups using the χ^2 test for categorical variables and the Wilcoxon rank-sum test for continuous variables. Unadjusted outcomes were compared between ICU groups overall and stratified by STS-EACTS category using the χ^2 test for categorical variables and the Wilcoxon rank-sum test for continuous variables. Multivariable logistic and linear regression then were used to evaluate the association of CICU with outcome adjusting for other patient and center factors. The method of generalized estimating equations was used to account for correlation between outcomes of patients at the same center. All models were adjusted for patient age, weight-for-age *z* score, the presence of any noncardiovascular or genetic abnormality or other preoperative factors (as defined above), preoperative length of stay 2 days or longer, any previous cardiothoracic surgery, STS-EACTS risk category, and center volume. Mortality and postoperative complications were evaluated in logistic regression models, with odds ratios and 95% confidence intervals reported. Length of stay was evaluated using linear regression and was log transformed for analysis because it was not normally distributed. Results from this model were reported as the difference in log length of stay in the CICU group versus other ICU group with 95% confidence intervals. Outcomes were modeled in the overall cohort and in each STS-EACTS risk category in stratified analysis. In the analysis of STS-EACTS category 5, centers that did not perform any procedures in this category ($n = 5$) during the study period were excluded. Finally, we performed a sensitivity analysis, excluding the 4 highest-volume centers from the analysis (who all had a CICU) and reran the model for the primary outcome variable (mortality) in the overall cohort. Missing data in the included study population were rare (<0.7% for all variables). Patients with missing data for a study end point were excluded from analysis involving that end point. All analyses were performed using SAS version 9.2 (SAS Institute, Cary, NC). $P < .05$ was considered statistically significant.

RESULTS

Patient and Center Characteristics

A total of 20 922 patients from 47 centers (28% in the Southeast, 19% in the Midwest, 19% in the Southwest, 15% in the Northeast, 13% in the Northwest, and 6% in the West) were included (25 centers with a CICU [$n = 14\,037$] and 22 centers in the “other ICU” group [$n = 6885$]). The 2 ICU groups were similar regarding patient gender, weight-for-age *z* score, and number of previous cardiothoracic surgeries (Table 1). The CICU group had slightly younger patients, a greater proportion of patients in higher STS-EACTS categories, and included a greater proportion of higher-volume centers. The other ICU group had a greater proportion of patients with noncardiac or genetic abnormalities and other preoperative factors.

TABLE 1 Patient and Center Characteristics

Variable	Overall, $n = 20922$	CICU, $n = 14037$ (25 centers)	Other ICU, $n = 6885$ (22 centers)	P
Age, median (interquartile range), mo	6.6 (1.1–46.8)	6.3 (1.0–44.4)	7.3 (1.4–54.0)	<.0001
Male, *n* (%)	11426 (54.6)	7678 (54.7)	3748 (54.4)	.72
Weight, median (interquartile range), kg	6.5 (3.7–15.1)	6.3 (3.6–14.7)	6.8 (3.8–16.5)	<.0001
Weight-for-age *z* score, median (interquartile range)	−1.07 (−2.1 to −0.1)	−1.08 (−2.1 to −0.1)	−1.04 (−2.0 to −0.1)	.02
Any noncardiac abnormality, *n* (%)	6182 (29.6)	4003 (28.5)	2179 (31.7)	<.0001
Any preoperative risk factor, *n* (%)	5788 (27.7)	3664 (26.1)	2124 (30.9)	<.0001
Pre-operative length of stay ≥2 days, *n* (%)	7147 (34.2)	4958 (35.3)	2189 (31.8)	<.0001
≥1 prior cardiothoracic surgery, *n* (%)	4677 (22.4)	3173 (22.6)	1504 (21.8)	.20
STS-EACTS risk category, *n* (%)				
1	7522 (36.0)	4873 (34.7)	2649 (38.5)	<.0001
2	5707 (27.3)	3772 (26.9)	1935 (28.1)	
3	2475 (11.8)	1716 (12.2)	759 (11.0)	
4	4234 (20.2)	2941 (21.0)	1293 (18.8)	
5	984 (4.7)	735 (5.2)	249 (3.6)	
Annual center volume				
Median number of operations per year (interquartile range)	160 (104–259)	209 (147–312)	118 (78–178)	<.001
<150	22 (46.8)	7 (28.0)	15 (68.2)	<.01
150–249	12 (25.5)	7 (28.0)	5 (22.7)	
250–349	9 (19.2)	7 (28.0)	2 (9.1)	
≥350	4 (8.5)	4 (16.0)	0 (0)	

Outcomes

Unadjusted outcomes are displayed in Table 2. Overall, unadjusted mortality was 3.6% (CICU) vs 4.1% (other ICU) ($P = .04$). There was a statistically different, although likely clinically insignificant, difference in length of stay between ICU groups and no difference in complications. Adjusted outcomes are displayed in Fig 1. In multivariable analysis, there was no difference in mortality comparing CICUs versus other ICUs overall. In stratified analysis, CICUs were associated with significantly lower mortality in STS-EACTS category 3. The most commonly performed procedures in STS-EACTS category 3 were complete atrioventricular canal repair ($n = 913$ procedures [37%]) and the arterial switch operation for transposition of the great arteries ($n = 559$ procedures [23%]). Mortality for these surgeries in the CICU versus other ICU group was 1.2% vs 3.4% ($P = .05$) and 0.3% vs 5.6% ($P < .0001$), respectively. In multivariable analysis, there was no difference between the 2 ICU groups in postoperative length of stay or complications overall or in stratified analysis (Fig 1).

In a sensitivity analysis excluding the 4 highest-volume centers (which all had a CICU), results in the overall cohort for the primary outcome of mortality were similar to the initial results (adjusted odds ratio: 0.89 [95% confidence interval: 0.64–1.22]; $P = .5$).

TABLE 2 Unadjusted Outcomes, Overall and Stratified by STS-EACTS Risk Category

Variable	Overall, $n = 20922$	CICU, $n = 14037$	Other ICU, $n = 6885$	P
In-hospital mortality, *n* (%)				
Overall	748 (3.8)	500 (3.6)	284 (4.1)	.04
STS-EACTS 1	40 (0.5)	20 (0.4)	20 (0.8)	.05
STS-EACTS 2	116 (2.0)	69 (1.8)	47 (2.4)	.13
STS-EACTS 3	75 (3.0)	38 (2.2)	37 (4.9)	<.001
STS-EACTS 4	360 (8.5)	237 (8.1)	123 (9.5)	.12
STS-EACTS 5	193 (19.6)	136 (18.5)	57 (22.9)	.14
Postoperative length of stay, median (interquartile range)				
Overall[a]	6 (4–13)	6 (4–13)	6 (4–13)	<.01
STS-EACTS 1	4 (3–6)	4 (3–6)	4 (3–6)	.14
STS-EACTS 2	6 (4–11)	6 (4–10)	6 (4–11)	.06
STS-EACTS 3	8 (5–15)	8 (5–15)	8 (5–15)	.89
STS-EACTS 4	12 (7–24)	12 (7–23)	13 (7–26)	.25
STS-EACTS 5	25 (14–46)	24 (14–43)	30 (16–52)	.03
Postoperative complications, *n* (%)				
Overall	4291 (20.5)	2879 (20.5)	1412 (20.5)	.99
STS-EACTS 1	764 (10.2)	473 (9.7)	291 (11.0)	.08
STS-EACTS 2	925 (16.2)	608 (16.1)	317 (16.4)	.80
STS-EACTS 3	612 (24.7)	410 (23.9)	202 (26.6)	.15
STS-EACTS 4	1438 (34.0)	979 (33.3)	459 (35.5)	.16
STS-EACTS 5	552 (56.1)	409 (55.7)	143 (57.4)	.62

[a] 10% trimmed means for length of stay. Overall: 8.5 days, CICU: 8.5 days, other ICU: 8.4 days.

DISCUSSION

Nearly half of US centers now deliver care to patients undergoing congenital heart surgery in a dedicated CICU.[4] In this multi-institutional study

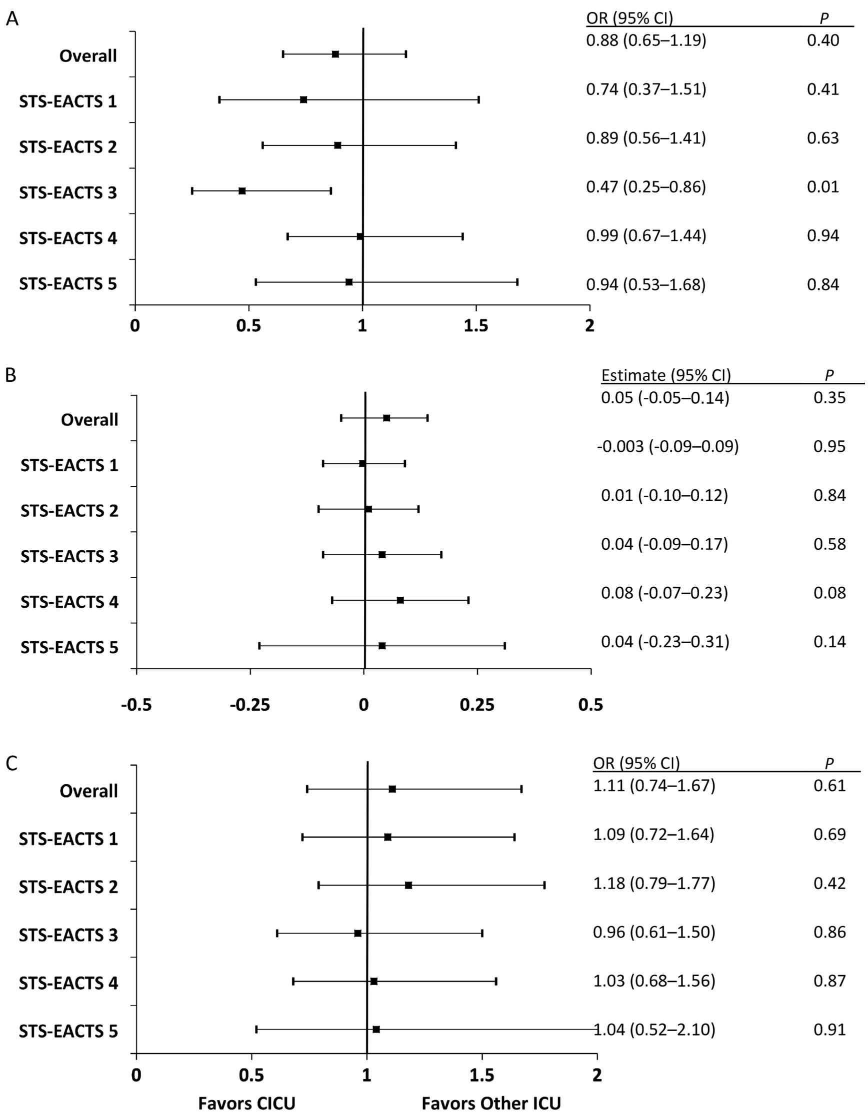

FIGURE 1

Adjusted outcomes associated with a CICU; overall and stratified by STS-EACTS risk category. A, In-hospital mortality. B, Postoperative length of stay (log days). C, Postoperative complications. OR indicates odds ratio; CI, confidence interval.

of more than 20 000 patients, we did not detect a difference in mortality, length of stay, or complications associated with the presence of a dedicated CICU in the overall cohort undergoing congenital heart surgery. There may be a survival benefit in certain subgroups.

Previous adult studies[6,21] support the notion that specialized care may improve outcomes. Reports from as early as the 1960s demonstrated improved outcomes in adults with acute myocardial infarction after the establishment of dedicated coronary care units. Improved outcomes also have been reported in adult stroke patients cared for in dedicated stroke units independent of stroke severity.[6–8,21,22] Other studies have demonstrated reductions in morbidity and mortality for patients with intracerebral hemorrhage treated in a neurosurgical ICU.[9]

Few pediatric studies have evaluated whether cohorting of patients or specialized care impact outcomes. Studies[10–12] of pediatric oncology patients have suggested that those treated at specialized cancer centers have improved survival. In pediatric asthma patients, a program involving cohorting of patients in a dedicated pulmonary unit staffed by asthma-trained personnel, the use of standardized treatment protocols, consultation with the patient's primary physician, and case managers who facilitated care and communication with families, was shown to reduce length of stay, use of the emergency department, and readmissions.[13]

Previous studies in the congenital heart disease population have evaluated the association of certain center-level factors on outcomes after surgery. Numerous studies[23–28] have shown that center surgical volume is associated with outcome, particularly in patients undergoing high-risk procedures. In addition, Berry et al[29] reported that teaching-hospital status was associated with decreased mortality for children undergoing the Norwood operation.

In the present analysis, we found that ICU structure was not associated with outcome in the overall cohort of patients undergoing congenital heart surgery. It may be that other ICU-related factors, such as training and availability of personnel and use of standardized management protocols, are of greater importance compared with structure alone. Previous studies[30,31] have suggested that the 24-hour onsite presence of an attending critical care specialist decreases ICU morbidity and mortality in adult and PICU settings. Other studies[32] have demonstrated the importance of standardized management protocols. Davis et al[32] showed that implementation of a standardized postoperative care plan for 65 children undergoing atrial septal defect repair was associated with significant reductions in length of stay and total hospital charges. Fernandes et al[33] evaluated a more diverse population of 175 children undergoing heart surgery and found that patients treated according to a standardized recovery protocol had reduced length of stay and hospital costs. Standardized management also has been shown to improve outcome in high-risk cohorts, such as single-ventricle patients undergoing the Norwood operation.[34] Finally, it has been hypothesized that differences in nurse staffing and skill mix may be important institutional factors influencing outcome. However, in a large multicenter study, Hickey et al[35] found that whereas there was significant variation in ICU nursing characteristics, none of the nursing characteristics evaluated were significantly associated with postoperative mortality.

In the present analysis, although we did not find that the presence of a CICU was associated with improved outcomes in the overall cohort, there seemed to be a survival benefit for patients in STS-EACTS category 3, primarily related to patients undergoing complete atrioventricular canal repair and the arterial switch operation. The reason for the selective impact in this subgroup are unclear. It may be that in the higher-risk categories (STS-EACTS categories 4 and 5), the complexity of the procedure or patient-specific factors outweigh any center factors related to organization or structure of postoperative care. Alternatively, this could be a spurious finding. If there is a true difference in STS-EACTS category 3, it may be that the presence of a CICU is a surrogate marker for other factors, such as surgeon and center experience. Previous analyses[24,36] have suggested that higher center and surgeon case volume are associated with decreased morbidity and mortality in patients undergoing the arterial switch operation. We were able to adjust for the impact of center volume in our analyses; however, surgeon experience still may play a role. In addition, it may be that a multidisciplinary specialized care team associated with an CICU fosters earlier recognition and management of postoperative complications, such as pulmonary hypertension in patients undergoing complete atrioventricular canal repair.[37,38] Studies in the adult cardiac population have suggested that lower mortality rates in high-performing centers are due to significantly lower mortality associated with postoperative complications.[39]

Finally, in evaluating the impact of the shift toward care in dedicated CICUs, other factors beyond the scope of this study may require consideration. In a recent survey,[40] only 13.7% of critical nurses reported that they would chose to work exclusively in a CICU and reported feeling less prepared to care for patients with congenital heart disease. Thus, recruitment, retention, and training of nursing staff must be considered. The impact of ICU structure on physician training also has been recently evaluated. A survey of pediatric critical care fellowship programs found that programs with a CICU rotation had less time for other training such as sedation/pain management, toxicology, and surgical rotations.[41] Finally, we were unable to evaluate the impact of ICU type on resource use or hospital costs. However, given that length of stay and complications did not differ between the 2 ICU groups, significant differences in resource use may be unlikely.

Limitations

This study is subject to the limitations of all observational analyses. Data from the initial ICU survey were submitted voluntarily. To minimize self-reporting error, survey responses were independently verified. Our analytic strategy attempted to account for known patient and center confounders. However, there may be other unmeasured patient confounders that we were unable to account for. For example, the database currently does not capture data on interventional catheterization procedures so we were unable to account for things such as preoperative balloon atrial septostomy in the patients undergoing arterial switch operation. There also is likely variation between centers in many aspects of care. We attempted to account for this and other center-related differences by adjusting for center-level factors and accounting for intrahospital variation by treating observations within a hospital as clustered (correlated) observations. In addition, the small number of patients and events, particularly in the lower STS-EACTS categories in our stratified analysis, likely limited our power to detect small, but perhaps clinically significant, differences in outcome.

This study focused only on a subset of US centers and also may be limited by selection bias, although the geographic diversity, range of center volume, and similarity in outcomes to the overall cohort included in the STS Congenital Heart Surgery Database support the generalizability of our results. In addition, our analysis was limited to assessment of in-hospital outcomes, and we were not able to assess whether differences in ICU structure impacted longer-term outcomes. Finally, allthough this study focused on ICU structure alone, there are likely several other important ICU-related factors such as staffing, training, and availability of personnel and use of standardized management protocols, as discussed above, that also may be important and require additional evaluation.

CONCLUSIONS

In this large multi-institutional study, we were not able to detect a difference in postoperative outcomes associated with the presence of a dedicated CICU in the overall cohort undergoing congenital heart surgery. There may be a survival benefit for certain subgroups. Additional investigation focusing not only on ICU structure, but also differences in personnel and care processes, is warranted to elucidate other ICU-related factors that may impact outcome in this population.

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